



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**ATTORNEY DOCKET NO. 028685-0104**

Applicant: Carl J. PEPINE et al.  
Title: COMBINATION DRUG THERAPY FOR TREATING  
HYPERTENSION  
Appl. No.: 10/816,461  
Filing Date: 04/01/2004  
Examiner: Unassigned  
Art Unit: 1614

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to OG Notice dated August 5, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

### **TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-1741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-1741.

Respectfully submitted,

October 18, 2004

Date

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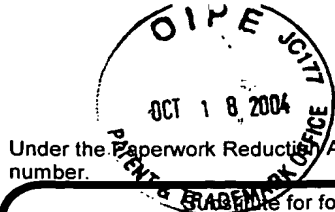
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Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  Date Submitted: October 18, 2004  (use as many sheets as necessary)		<b>Complete if Known</b>	
		<b>Application Number</b>	10/816,461
		<b>Filing Date</b>	TBD
		<b>First Named Inventor</b>	Carl J. PEPINE et al.
		<b>Group Art Unit</b>	1614
		<b>Examiner Name</b>	Unassigned
		<b>Attorney Docket Number</b>	028685-0104

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		U.S. 4,933,361		Urbach et al.	Jun-12-1990	
		U.S. 5,098,910		Becker et al.	Mar-24-1992	
		U.S. 5,236,933		Becker et al.	Apr-17-1993	
		U.S. 5,366,994		Becker et al.	Nov-22-1994	
		U.S. 5,403,856		Henning et al.	Apr-04-1995	
		U.S. 5,500,434		Becker et al.	Mar-19-1996	
		U.S. 5,684,016		Henning et al.	Nov-04-1997	
		U.S. 5,721,244		Becker et al.	Feb-24-1998	
		U.S. 5,744,496		Henning et al.	Apr-28-1998	
		U.S. 5,747,504		Henning et al.	May-05-1998	

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
		H.A. PUNZI ET AL., The Treatment of Severe Hypertension with Trandolapril, Verapamil, and Hydrochlorothiazide, <i>Journal of Human Hypertension</i> (1997) 11, 477-481.	
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Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet 2 of 5	Attorney Docket Number	028685-0104	

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Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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